

REMARKS

With this amendment, claims 1-81 are canceled and new claims 82-94 are added. Accordingly, claims 82-94 will be pending upon entry of this amendment.

In the September 7, 2005 Office communication, the Examiner extended the courtesy of notifying applicants that the amendment as filed on June 14, 2005, is considered to be non-compliant because the amendment fails to conform to the amendment format as required by 37 CFR § 1.121. This notification is gratefully acknowledged. This amendment adheres to the telephone recommendation of Examiner Gambel to cancel all previously presented claims in the application, and add any claims to be considered by the Examiner as new claims.

Support for new claims 83-94 is identical to the support for claims 70-81 already of record in the amendment filed on March 2, 2005. Support for new claim 82 is identical to the support for claim 69 already of record in the supplemental amendment filed June 14, 2005. For the Examiner's convenience, this support is herein restated for the new claims.

"Allowable" claim 67 of the December 3, 2004 Office action was directed to a method of reducing T cell responsiveness *in vivo* to an autoantigen expressing cell, which method comprises administering to a subject in need of such treatment: (a) an antigen-presenting cell that presents an autoantigen; and (b) an anti-gp39 antibody, wherein the anti-gp39 antibody is MR1 produced by the hybridoma having ATCC Accession No. HB 11048 and is administered prior to, concurrent with, or subsequent to administration of the antigen-presenting cell in an amount effective to reduce T cell responsiveness to the antigen-presenting cell.

Claim 82 is directed to a method for reducing T cell responsiveness *in vivo* to an autoantigen expressing cell, which method comprises administering to a subject in need of such treatment: (a) an antigen-presenting cell that presents an autoantigen; and (b) an anti-gp39 antibody which binds to an antigen, which antigen: (i) is bound by a CD40-immunoglobulin (CD40-Ig) fusion protein; (ii) is present on activated but not resting T-cells; and (iii) has the same molecular weight as a protein precipitated by the CD40-Ig fusion protein, wherein the anti-gp39 antibody is administered prior to, concurrent with, or subsequent to administration of the antigen-

presenting cell in an amount effective to reduce T cell responsiveness to the antigen-presenting cell.

Claim 82 refers to and defines the recited antigen by its binding to CD40-Ig as feature (i), in addition to recited features (ii) and (iii). As is the case for MR1 binding, the feature of CD40-Ig binding provides a fully-characterized antigen which adequately defines the anti-gp39 antibody genus of step (b). This result is in accord with the recent case law of the Federal Circuit for defining a genus of antibodies, and in accord with the Synopsis of Application of Written Description Guidelines relied upon by that court. *Noelle v. Lederman*, 355 F.3d 1343, 1349-50 (Fed. Cir. 2004).

This contention is particularly true where, as here, the antigen *itself* was well known in the art at the time of invention, including the structure of its primary amino acid sequence. *See e.g.*, Hollenbaugh et al., 1992, "The human T cell antigen gp39, a member of the TNF gene family, is a ligand for the CD40 receptor: expression of a soluble form of gp39 with B cell co-stimulatory activity," *The EMBO Journal* 11, 4313-4321 (reference CCR of record; cited *inter alia* at page 2, lines 30 and 36, and at page 7, line 8 of the specification). Moreover, the antibody genus *per se* of step (b) is *not* being claimed. Rather, the claims are directed to *methods* for reducing T cell responsiveness.

Support for claim 82 is found throughout the specification as filed, for example, in Figures 9-11, at page 6, line 35, page 9, lines 16-19, at page 29, lines 2-4, page 28, lines 15-18, and especially page 27, lines 20-21.

New claims 83-94 depend from claim 82. Support for all new claims is found throughout the specification as originally filed, for example, as indicated below.

New claims 83, 84, 90 and 91 are directed to the method of claim 82 in which the antigen-presenting cell is selected from the group consisting of B lymphocytes, monocytes, dendritic cells, Langerhans cells, keratinocytes, endothelial cells, astrocytes, fibroblasts and oligodendrocytes. Support for this claim can be found at page 9, lines 37-39 and page 10, line 1.

New claim 85 is directed to the method of claim 84 in which the antigen-presenting cell is an activated B lymphocyte. Support for this claim can be found at page 10, lines 28-31 and Example 1 at page 14.

New claim 86 is directed to the method of claim 85 in which the antigen-presenting cell is a splenic activated B lymphocyte. Support for this claim can be found in Example 1 at page 14.

New claim 87 is directed to the method of claim 82 in which the antigen-presenting cell is a lymphoid cell. Support for this claim can be found at page 10, lines 8-9.

New claims 88 and 89 are directed to the method of claim 82 in which the antigen-presenting cell is a peripheral blood lymphocyte or a bone marrow cell, respectively. Support for these claims can be found at page 10, lines 35-38.

New claim 92 is directed to the method of claim 82 in which the anti-gp39 antibody is an anti-human gp39 antibody. Support for this claim can be found at page 27, in Example 6, Experiment 1.

New claims 93 and 94 are directed to the method of claim 82 in which the anti-gp39 antibody is a humanized anti-human gp39 antibody or a chimeric anti-human gp39 antibody, respectively. Support for these claims can be found at page 8, lines 16-26.

No new matter has been added by way of this amendment.

CONCLUSION

In view of the foregoing amendment and remarks, all claims in this application are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. If any issue remains in connection herewith, the Examiner is respectfully invited to call the undersigned to discuss same.

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Respectfully submitted,

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